Patent protection for pharmaceutical products

Background Paper

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PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS

Margaret Smith
Law and Government Division

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INTRODUCTION

Patent protection is crucial to the innovative pharmaceutical industry. Innovative companies require the guaranteed period of market exclusivity afforded by patents in order to sustain drug prices, recoup research and development (R&D) expenditures and finance the development of new products.

Like other inventions, medicines are entitled to patent protection if they meet certain requirements. Unlike other products, however, medicines are required to undergo a strict regimen of tests and evaluations to determine their safety and efficacy before they can be sold commercially. The testing process is rigorous and time-consuming, involving animal and clinical trials of each prospective new drug. Much of the testing takes place after a patent for a drug has been applied for and results in significant lag between the invention of the drug and its sale to the public. Meeting government-imposed regulatory requirements consumes part of the period of patent protection, so that this is shorter for the pharmaceutical sector than for other industries.

Innovative companies have responded to this disadvantage by lobbying vigorously for measures to strengthen the patent system and for changes to the regulatory process that would decrease the time involved in obtaining marketing approval for a drug.

This paper focuses on measures taken in Canada and the United States to extend patent protection for pharmaceutical products. Developments in the European Community, Japan and Australia will also be described.

PATENT PROTECTION FOR MEDICINES IN CANADA

A. History of Compulsory Licensing

Prior to the 1987 amendments to the *Patent Act*, the basic patent term for a medicine in Canada was 17 years from the patent date. Pharmaceutical patents, however, were subject to licensing to other manufacturers. In 1923, the *Patent Act* was amended to provide for compulsory licensing for manufacturing purposes of food and drug patents. The amendment provided that:

> In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner shall, unless he sees good reason to the contrary, grant to any person applying to the same licence limited to the use of the invention for the purposes of the preparation or production of food or medicine but not otherwise; and, in settling the terms of such licence and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving the inventor due reward for the research leading to the invention.[1]

Because compulsory licences under this provision were available only where a medicine's active ingredients were manufactured in Canada and because generic drug producers had neither the capacity nor the willingness to manufacture chemical ingredients, they were rarely used. In fact, from 1935 to 1969 only 22 licences were granted.[2]

In the 1960s, several commissions examined compulsory licensing under the *Patent Act*. First, the Isley Commission recommended that both product patents and compulsory licensing be permitted for pharmaceutical patents.[3] A few years later, the Restrictive Trade

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(1) *Patent Act*, S.C. 1923, c. 23, s. 17.

(2) Canada, Commission of Inquiry on the Pharmaceutical Industry, *The Report of the Commission of Inquiry on the Pharmaceutical Industry*, Minister of Supply and Services, Ottawa, 1985, p. 14-15 (hereafter referred to as the Eastman Commission).

(3) Canada, Royal Commission on Patents, Copyright and Industrial Design, *Report on Patents of Invention*, Queen's Printer, Ottawa, 1960, p. 92-97.

Practices Commission recommended that drug patents be abolished.[4] In 1964, the Royal Commission on Health Services called for the maintenance of pharmaceutical patents, along with the creation of reasonable mechanisms for granting compulsory licences for importation purposes.[5] Finally, some two years later, the House of Commons Special Committee on Drug Costs and Prices recommended that the *Patent Act* be amended to allow for "... compulsory licences to import drug products in all forms ..."[6]

In 1969, the *Patent Act* was amended to permit compulsory licences to import medicines into Canada. Among other things, the amendment provided that the Commissioner of Patents was to issue compulsory licences to import medicines and to fix the royalty for such licences unless there was good reason to deny the application. The Commissioner had little discretion in granting compulsory licences. Royalty rates were set at 4% of the net selling price of a drug in its final dosage form in arm's length purchases.

The ability to obtain licences to import and to sell copies of patented medicines fostered the establishment of a number of generic drug manufacturers producing and selling lower-priced alternatives to the drugs produced by brand-name companies. The generic sector also advanced in the wake of provincial government programs to reimburse the cost of drugs to certain persons such as senior citizens and recipients of social assistance and legislation that required pharmacists to fill prescriptions with the generic equivalent of higher-priced patented medicines.

Seeing some of their best-selling and most profitable products subject to generic competition, brand-name manufacturers began to seek changes to the compulsory licensing regime.

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(4) Canada, Department of Justice, Restrictive Trade Practices Commission, *Report Concerning the Manufacture, Distribution and Sale of Drugs*, Queen's Printer, Ottawa, 1963, p. 516-524.

(5) Canada, Royal Commission on Health Services, *Report of the Royal Commission on Health Services*, Queen's Printer, Ottawa, 1964, Vol. 1, p. 701-709.

(6) Canada, House of Commons, Special Committee on Drug Costs and Prices, Second (Final) *Report of the Special Committee of the House of Commons on Drug Costs and Prices*, Ottawa, Queen's Printer, 1966/67, p. 42.

In 1983, the then Minister of Consumer and Corporate Affairs called for a rebalancing of the 1969 policy on compulsory licensing in order to generate growth in the pharmaceutical industry. Three approaches to changing the *Patent Act* were put forward. These were: (1) variable royalty rates where compulsory licences would be granted but rates set to reflect the level of research and development activity carried out in Canada; (2) market exclusivity, where compulsory licences to import would be granted only after a specified number of years had elapsed; and (3) exempting from the granting of compulsory licences those companies that gave performance and price commitments.[7]

In 1984 the federal government established the Commission of Inquiry on the Pharmaceutical Industry (Eastman Commission), part of whose mandate was to make recommendations for patent protection for the pharmaceutical industry. The Commission found that compulsory licensing had not caused a decline in the economic health of the patent-holding firms as a whole, although it had adversely affected the profitability of firms whose products were subject to generic competition.[8] The Commission felt that patent-holding firms would benefit from protection from generic competition, particularly where early compulsory licensing reduced the potential profits of a patent-holding firm so much as to make it unattractive to introduce the drug on the market.[9]

The Commission recommended that an owner of a patent for a medicine be granted a short period of market exclusivity (four years) from the date when a new drug received a Notice of Compliance (NOC) authorizing marketing.[10] The Commission concluded that this period of exclusivity would allow brand-name manufacturers to set prices without competition, develop sales and recoup development and promotional costs. The Commission also recommended that royalties paid under compulsory licences should be put into a special royalty

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(7) Margaret Smith, *Bill C-22: Compulsory Licensing of Pharmaceuticals*, Mini-Review 86-36E, Research Branch, Library of Parliament, 24 November 1986, p. 2-3.

(8) Eastman Commission (1985), p. 349.

(9) *Ibid.*, p. 352.

(10) A Notice of Compliance, which formally authorizes a drug to be sold, is issued by the Department of Health after the drug has met the requisite safety and efficacy requirements.

fund. The royalty rate would be determined in accordance with a formula that took into account the value of a licensee's sales of compulsorily licensed products in Canada, the pharmaceutical industry's world-wide ratio of research and development to sales, plus 4%. Distributions from the fund to firms whose patents were compulsorily licensed were to be based on the relative research intensity of those firms.[11]

B. Bill C-22 (*Patent Act* Amendments, 1987)

In November 1986, a bill to amend the *Patent Act* (Bill C-22) was introduced in the House of Commons. The bill, which became law in late 1987,[12] made several long-needed technical changes to Canadian patent law, and substantially altered the compulsory licensing regime for patented medicines.

The bill guaranteed the holders of patents for medicines a period of protection from compulsory licences. After 27 June 1986, a brand-name manufacturer receiving an NOC for a drug was assured 10 years of protection against compulsory licences to import and seven years of protection against compulsory licences to manufacture. Patented medicines for which NOCs had been issued on or before 26 June 1986, and for which generic producers had obtained either NOCs or compulsory licences but not both, were entitled to seven years' protection against compulsory licences to import. Patented medicines for which NOCs had been issued on or before 27 June 1986, but for which neither compulsory licences nor generic NOCs had been issued had eight years of protection against compulsory licences to import.

The Act granted additional protection to drugs invented and developed in Canada: compulsory licences to import could not be granted, but compulsory licences to manufacture could be, if, after seven years from the date of the NOC for the drug, the inventor failed to make the drug in Canada for the purpose of substantially or completely supplying the Canadian market.

Bill C-22 also provided for the creation of the Patented Medicine Prices Review Board (PMPRB), an independent quasi-judicial body with a mandate to ensure that the prices

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(11) Eastman Commission (1985), p. 363.

(12) R.S., 1985, c. 33 (3rd Supp.).

charged by patentees for patented medicines are not excessive. It was to report annually on pricing trends in the pharmaceutical industry and on the ratios between research and development expenditures and sales, both for individual patentees and for the entire patented pharmaceutical sector.[13] The Board's authority to review prices is limited to patented medicines sold in Canada for human or veterinary use. It does not include drugs for which there are no Canadian patents or generic drugs sold under compulsory licence. The Board reviews a medicine's factory-gate price -- the price at which a patentee sells the medicine directly to a hospital or pharmacy; retail prices are not subject to the Board's jurisdiction.[14]

Prior to the passage of Bill C-22, Canada granted process patents for medicines; patents were granted not for the chemical compound or medicine itself, but for the process by which the compound was made. Thus, patent protection extended to the product only if it was made by the patented process. Process patents are considered to be a rather weak form of protection, since someone other than the patentee would be able to manufacture the compound without infringing the patent, by finding a way to make it by a different process. Bill C-22 altered the process patent regime to permit the granting of product patents for pharmaceutical products. As a result, the product itself is protected, regardless of the process used.

Another change to the general patent law also affected patents for pharmaceuticals. As mentioned earlier, prior to the passage of Bill C-22, patents were granted in Canada for a period of 17 years from the date the patent was issued. With the passage of the bill, Canada moved to a "first-to-file" system; this established a patent term of 20 years commencing from the date on which a patent application is filed.

Bill C-22 was contentious and its passage was delayed several months by the Senate. The most widespread criticism of the bill was its potential effect on drug prices. Several provincial governments argued that, over time, the delay in the introduction of generic drugs would increase the costs of operating health care plans. Others suggested that there would be an adverse effect on private insurers and consumers generally.[15] Doubts were cast on the

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(13) Canada, Patented Medicine Prices Review Board, *Fourth Annual Report, For the Year Ended December 31, 1991*, Minister of Supply and Services, Ottawa, 1992, p. 4.

(14) *Ibid.*, p. 4-5.

(15) Senate of Canada, Proceedings of the Special Committee of the Senate on the Subject-matter of Bill C-22, *Third Report of the Committee*, 27 June 1987, 18:8-9.

ability of the PMPRB to keep drug price increases below the rate of change in the Consumer Price Index and to ensure that introductory prices of new drugs would be reasonable.

In return for the additional exclusivity offered by Bill C-22, the Pharmaceutical Manufacturers Association of Canada (PMAC), representing most of the manufacturers of brand-name drugs, stated that its members would boost levels of research and development (R&D) in Canada to 8% of sales by the end of 1991 and 10% of sales by the end of 1996. Opponents of the bill were critical of this commitment; they doubted that PMAC members would achieve their R&D goals and were concerned that the bill did not ensure that these commitments would be met.(16) Some felt that the goal of a 10% ratio of R&D to sales was too low. In its report for the year ended 31 December 1991, the PMPRB stated that PMAC members had achieved an R&D:sales ratio of 9.6% in 1991.

C. Intellectual Property Protection under the GATT and NAFTA

Subsequent to the passage of Bill C-22, further developments in the area of patent protection took place in the context of the GATT multilateral trade talks and the North American Free Trade Agreement (NAFTA) negotiations. In January 1992, the federal government endorsed proposals in the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations that, among other things, would increase the effective patent protection for manufacturers of pharmaceutical products. The proposals would allow the owners of pharmaceutical patents to enjoy the same protection as is granted to patent owners generally. Thus, Canada could no longer maintain its system of compulsory licensing for pharmaceuticals or discriminate between Canadian- and foreign-invented products. The draft text, however, provided that compulsory licences issued before the date the agreement became known (20 December 1991) would continue in full force and effect.

The North American Free Trade Agreement repeated many of the provisions of the Uruguay Round draft intellectual property proposals including the provisions dealing with non-discrimination of patent rights and, like the draft text, provided that compulsory licences issued before 20 December 1991 would continue to be valid.

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(16) *Ibid.*, p. 18:12.

D. The Patent Act Amendment Act, 1992

In June 1992 the federal government moved to legislate in relation to the GATT and NAFTA provisions on intellectual property by introducing Bill C-91, *The Patent Act Amendment Act, 1992*.[17] The bill received Third Reading in the House of Commons in late 1992, was passed by the Senate on 3 February 1993 and received Royal Assent on 4 February 1993.

The Act provides that compulsory licences for medicines can no longer be granted. Thus, generic producers will not be able to market a copy of a patented medicine until the patent has expired. Compulsory licences in existence before 20 December 1991, however, continue in effect and are subject to the seven- and ten-year limitation periods established under Bill C-22. Licences granted after 20 December 1991 but before the day the Act came into force were terminated when the Act became effective.

The Act does, however, allow a person to make, use or sell a patented product before the patent expires without infringing a patent where the use is reasonably related to the development and submission of information required under laws that regulate that product. Thus, a generic manufacturer can use the patented product to proceed with the necessary tests and procedures to obtain an NOC from the Department of Health. Moreover, the generic firm will not be infringing a patent if, during the six month period prior to the expiration of a patent, the manufacturer makes use of the patent to stockpile generic copies of the patented product for sale after the patent expires.[18]

Under the Act, the Governor in Council (Cabinet) has authority to make regulations to prevent infringement in the above-mentioned circumstances. Among other things, the regulations can: (a) establish the conditions that must be fulfilled before a notice or certificate pertaining to a product can be issued to a patentee or to any other person; (b) set the earliest date on which a notice issued to a person other than a patentee might take effect; (c) outline provisions to govern the resolution of disputes between patentees and any other person

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(17) Statutes of Canada 1993, C. 2.

(18) *Patent Act*, s. 55.2(2) as enacted by S.C.1993, c.2, s.4. *Manufacturing and Storage of Patented Medicines Regulations*, SOR/93-134, 12 March 1993.

who applies for a notice; and (d) confer rights of action in the court with respect to such disputes.[19]

The *Patented Medicines (Notice of Compliance) Regulations*,[20] issued on 12 March 1993, detail how these provisions will operate and provide that the Minister of Health will not issue a Notice of Compliance to a generic manufacturer until all relevant patents pertaining to the medicine have expired. The regulations also set out procedures for dealing with claims contesting the validity of patents. Where a patent owner commences a legal action to enforce its patent, the granting of an NOC can be postponed for up to 30 months, pending resolution of the action.

E. Legislative Patent Extensions

In addition to general patent legislation, patent rights can be extended by an Act of Parliament according an extension of a particular patent to a particular patent holder. Although it seldom acts to extend patent rights in this manner, Parliament considered two such extensions in the late 1980s. In 1987, Bill C-259, to extend the patent term for the food additive aspartame for a period of five years, was passed by the House of Commons. The bill was subsequently amended in the Senate but the House of Commons did not accept the amendment and the bill never became law. Bill C-22, passed by Parliament in 1987, effectively extended the market exclusivity of the drug Diltiazem hydrochloride by providing that any generic manufacturer receiving a compulsory licence for the drug could not exercise any rights under the licence until 28 March 1989.

PATENT PROTECTION FOR MEDICINES IN THE UNITED STATES

A. The *Drug Price Competition and Patent Term Restoration Act* of 1984

In the United States, the basic patent term for prescription drugs is 17 years from the date a patent is granted. Although concerns over the high cost of prescription drugs fostered

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(19) *Ibid.*, s. 55.2(4).

(20) *Patented Medicines (Notice of Compliance) Regulations*, 12 March 1993, SOR/93-133.

several attempts during the 1960s and the 1970s to reduce the period of patent protection for pharmaceuticals, none of these was successful. In the early 1980s, the drug manufacturers, arguing that regulatory delays reduced the effective life of their patents, began to push for an extension of the patent term. A number of bills to achieve this were introduced in Congress, but all met with substantial opposition from consumer and other groups.(21) The generic drug sector and consumer groups also rallied support for reforms to allow generic drugs to come on the market as soon as possible after expiration of the relevant patents.

The issues of patent term extension and early market entry for generic drugs were addressed in the *Drug Price Competition and Patent Term Restoration Act*, (hereafter referred to as the "*Restoration Act*") which became law in 1984.(22) The Act provided for an abbreviated application for the approval of generic drugs so that they would be available more quickly after the expiration of a patent.(23) In order to expedite the market entry of generic drugs, generic manufacturers could use an unexpired drug patent in preparing their application for Food and Drug Administration (FDA) approval without risking a legal action for patent infringement.(24)

For the brand-name drug manufacturers, the most important provisions of the *Restoration Act* were those providing for an extension of a drug's patent term based upon the time taken to satisfy FDA regulatory requirements.

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(21) Ronald L. Desrosiers, "The Drug Patent Term: Longtime Battleground in the Control of Health Care Costs," *New England Law Review*, Vol. 24, Fall 1989, p. 133-134.

(22) Public Law No. 98-417, 98 Stat. 1585 (1984).

(23) The *Restoration Act* provides that the Food and Drug Administration must approve an abbreviated new drug application for a generic drug within 180 days from the time of filing, provided the applicant shows that: (1) the conditions for prescribed, recommended or suggested use for the generic medicine were approved for a previous drug; (2) the active ingredients of the generic drug are the same as those of the previously approved drug; (3) the generic drug uses the same route of administration, dosage form and strength as the previous drug; (4) the generic drug is bioequivalent to its brand-name counterpart; and (5) the proposed labelling for the generic product is the same as for that of the previously approved drug.

(24) Ellen J. Flannery and Peter Barton Hutt, "Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984," *Food Drug Cosmetic Law Journal*, Vol. 40, No. 3, July 1985, p. 308.

A number of conditions have to be met before an extension is granted. First, the patent term cannot have expired before an extension application is submitted. Second, the term must never have been extended before. Third, the product must have been the subject of a "regulatory review period" before it was sold to the public.[25] The life of a patent cannot be extended more than 14 years from the date a drug receives market approval and the maximum allowable extension for a patent is five years. The term will be extended by the regulatory review period taking place after the date the patent is issued; however, this period can include only one-half of the time used to conduct clinical trials after that date.

An applicant for a patent term extension is required to pursue the marketing approval process with due diligence.[26] If it can be shown that the applicant has not done so, the regulatory review period used to determine the term of a patent extension will be reduced by the period the applicant delayed pursuing the market approval.

As of April 1990, 85 products received patent extensions, but none of these extensions was for the entire five-year term permitted under the *Restoration Act*.[27]

B. The Orphan Drug Act

Passed in 1983, the *Orphan Drug Act* (ODA)[28] was designed to deal with the lack of financial incentives for drug manufacturers to develop drugs for individuals with rare illnesses. Under the Act a drug can be designated an "orphan" drug if it will be used to treat a condition or disease that affects fewer than 200,000 persons in the United States or affects more than that number but where there is no reasonable expectation of recovering from U.S. sales the development costs of the drug and the cost of making it available in the U.S. market.

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(25) Public Law No. 98-417, 98 Stat. 1585, (1984) s. 210(a).

(26) "Due diligence" is defined as the amount of attention, continuous effort and timeliness that one would reasonably expect from and would ordinarily be exercised by a person pursuing market approval for a drug.

(27) United States International Trade Commission, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, September 1991, p. 3-14.

(28) Public Law No. 97-414, 96 Stat. 2049 (1983).

The ODA provides a number of incentives to drug manufacturers. These range from grants for clinical testing and tax credits for clinical research and development costs to seven years of market exclusivity from the time a product is approved for a particular condition.[29]

C. Legislative Patent Extensions

Aside from the *Restoration Act*, Congress can pass laws to provide for patent extensions in specific cases. During the 1980s, five patent extension laws were enacted by Congress.[30] In 1991-1992, other requests for extensions came before Congress, but the bills died with the ending of the 102d Congress. One of these bills,[31] however, is worth mentioning because it sought to establish general standards for approving patent extension requests.

The bill would have divided requests for patent extensions into two groups -- requests resulting from delays in premarketing approval and other. To obtain approval where delay was involved, the patent holder would have had to demonstrate that it had suffered unjustified injury as a result of a delay in premarketing approval that was beyond its control and directly caused by misconduct on the part of the federal government. "Government misconduct" could have been "dishonest or deceitful conduct," "vindictive or retaliatory action," "arbitrary, capricious or grossly negligent performance of governmental duties" or "serious failure to perform governmental duties." The "unjustified injury" criterion could have involved "a substantial inequity to the patent holder who, without the extension of the patent term, will suffer material harm directly attributable to the delay in the approval process." The harm suffered by the patent holder would have had to be balanced against the public interest and thus would have

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(29) Patricia J. Kenney, "The Orphan Drug Act -- Is it a Barrier to Innovation? Does it Create Unintended Windfalls?" *Food Drug Cosmetic Law Journal*, Vol. 43, No. 4, July 1988, p. 667.

(30) Richard M. Cooper, "Legislative Patent Extensions," *Food and Drug Law Journal*, Vol. 48, No. 1, 1993, p. 63.

(31) H.R. 5475, 102d Congress, 2d Session (1992).

had to "outweigh any harm to the public (such as through higher prices) or to competitors that will result from extension of the patent."[32]

Where delay did not form the basis for a request, the patent holder would have had to demonstrate that it had suffered unjustified injury as a result of government misconduct or government action or inaction in order to create a moral or ethical obligation on the part of the government to provide relief.

Specific patent extensions are more common in the United States than Canada. It is likely that extension requests will continue to be made for situations where the *Restoration Act* cannot be used or does not allow for a sufficient extension period. Legislative extensions, however, are difficult to achieve since they are subject to the vicissitudes of the congressional system.

PATENT PROTECTION IN THE EUROPEAN COMMUNITY

The member states of the European Community grant patents in accordance with their national laws. Generally, the term of a patent is 20 years from the date a patent application is filed.

The Commission of the European Community brought forward a proposal for patent term restoration in 1990. Concerned that European innovative pharmaceutical firms might have less protection than their United States and Japanese competitors, the Commission proposed patent term extensions for up to 10 years, but not exceeding 16 years after a drug received marketing approval.[33] One of the principal goals of the Commission was to provide for uniform legislation throughout the Community so as to avoid creating disparities among member states and barriers to the free movement of medicines within the EC.

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(32) Sections of H.R. 5475 quoted in Richard M. Cooper, "Legislative Patent Extensions," *Food and Drug Law Journal*, Vol. 48, No. 1, 1993, p. 80-81.

(33) Heinz Redwood, *Pharmaceutical Patent Term Restoration For The 1990s*, Oldwicks Press, 1990, p. 73.

In June 1992, the Council of the European Communities adopted a regulation to provide for the creation of supplementary patent protection for medicines.(34) The regulation, which differs from the original Commission proposal, provides that pharmaceutical patents can be extended for a maximum period of five years thus allowing the patent holder to enjoy up to 15 years of market exclusivity from the time a drug is first brought on the market.(35)

The regulation sets out a number of conditions applicable to an extension. In order to obtain supplementary protection, the patent for the medicine must be in force and a valid authorization to market it in existence. A medicine will be entitled to only one supplementary patent certificate and an application for supplementary protection must be filed within six months of the date on which a patentee receives authorization to market the medicine.

SUPPLEMENTARY PATENT PROTECTION IN OTHER COUNTRIES

Other industrialized countries provide supplementary patent protection for pharmaceutical products. Under patent term restoration legislation that came into force in Japan in 1988 a patent term can be extended for up to five years, based on the time taken for regulatory review. Maintenance fees must be paid annually to keep the patent in force.(36)

In Australia, a patent relating to a pharmaceutical substance can be extended for a period of four years.(37) Compulsory licences can be issued if the "reasonable requirements of the public" with respect to the invention have not been satisfied and the patentee is not able to explain satisfactorily why the patent has not been exploited.(38)

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(34) Council Regulation (EEC) No 1768/92, *Official Journal of the European Communities*, No L/182/1. This regulation is binding and directly applicable to all Community members.

(35) *Ibid.*, Article 13.

(36) Redwood (1990), p. 67.

(37) *Patents Act 1990*, s. 75.

(38) *Ibid.*, s. 133.

THE REGULATORY REVIEW PROCESS AND PATENT TERMS

With the passage of the *Patent Act Amendment Act, 1992*, Canadian patents for medicines were placed on an equal footing with patents for other products -- patented medicines now enjoy 20 years of protection without the possibility of generic competition. As mentioned earlier, a considerable amount of time, currently about 10 years, or one-half of the life of a patent, is taken up with product development and obtaining Department of Health approval to market a medicine.(39) Commenting on drug regulation in Europe, one author notes that the effective life of a pharmaceutical patent has declined to between 13 and eight years, depending on the type of product.(40) Because a patentee cannot sell a drug until its safety and efficacy have been established, the effective period of market exclusivity provided by the patent is reduced.(41)

The impact on the pharmaceutical industry of delays in obtaining marketing approval has been examined in a number of Canadian studies. In 1985, the Eastman Commission noted that delays in obtaining approval to market new drugs postpones "the benefits that the public receives from therapeutic advances," reduces "the profitability of new drugs for

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(39) A potential new drug can undergo the following testing stages: the discovery stage where scientists discover new chemical entities that may warrant further testing; the second stage, where animal toxicity tests are conducted; and the manufacturer's filing of an Investigational New Drug Submission with the Department of Health to request permission to perform clinical trials on humans. The Department of Health also examines chemistry and manufacturing information submitted by the drug manufacturer. If permission for testing is granted, Phase I clinical trials will begin. At this stage, the drug is administered to a small number of healthy individuals to determine how they tolerate it. During Phase II the clinical effectiveness of the drug is tested on a greater number of people. Larger-scale testing on human beings takes place during Phase III trials, in order to evaluate the drug's safety and efficacy. Double-blind controlled clinical studies are also conducted. Data from these tests are submitted to the Department of Health for evaluation. If these are satisfactory, the department will issue a Notice of Compliance authorizing commercial sale of the drug.

(40) Leigh Hancher, *Regulating for Competition*, Clarendon Press, Oxford, 1990, p. 334.

(41) In 1985, it took about 700 days to obtain an NOC from the Department of National Health and Welfare; in 1991, the time had extended to about 1,160 days: Pharmaceutical Manufacturers Association of Canada, *Towards a Globally Competitive Research-Based Pharmaceutical Sector*, April 1992, p. 19.

innovative firms" and lessens "the attractiveness of Canada as a location for clinical research."[42] The Commission called for an acceleration of the drug clearance process.[43]

In order to foster more pharmaceutical R&D in Canada, the National Advisory Council on Pharmaceutical Research felt that Canada should attempt to achieve a faster review and approval process.[44] A 1992 report reviewing the Canadian drug approval system also contained a number of recommendations designed to create a more efficient drug approval process.[45] Acting on many of these recommendations, the Department of Health is taking measures to eliminate the backlog of applications and to reduce the review time to under one year.[46]

In the United States, the Food and Drug Administration is moving to streamline its drug approval process. In 1992, Congress enacted a new drug-approval plan. Widely supported by the pharmaceutical industry, the plan calls for pharmaceutical manufacturers to pay the U.S. government some $300 million in fees over the next five years.[47] In return, the FDA will hire several hundred new drug evaluators and halve, by October 1997, the time taken to evaluate the safety and effectiveness of drugs. Review times are expected to be reduced to 12 months for most new drugs and to six months for high priority new drugs to treat diseases such as AIDS and cancer.[48]

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(42) Eastman Commission (1985), p. 387.

(43) *Ibid.*, p. 389.

(44) Canada, Department of National Health and Welfare, National Advisory Council on Pharmaceutical Research, *Time to Act: A Strategy for the Development of a Growing Sector: Pharmaceutical Research*, 1991, p. 66.

(45) Denis Gagnon, Review of the Canadian Drug Approval System, *Working in Partnerships ... Drug Review for the Future*, July 1992. p. 31.

(46) Communication with Department of Health official, 3 November 1993.

(47) Prescription drug manufacturers will pay an initial fee for each drug application and an annual fee for each drug on the market and each operating plant. Fees will increase each year.

(48) Bruce Ingersoll, "Plan to Speed Drug Approvals Clears Congress," *Wall Street Journal*, 8 October 1992.

Changes to streamline and speed-up the drug review process and patent term restoration legislation serve to increase the effective life of drug patents and improve patent protection. Such measures are welcomed by patentees, who benefit from a longer period during which to sell their products free from generic competition.

CONCLUSION

The importance of patent protection to the pharmaceutical sector is evidenced by the fact that several multinational drug companies rank among the top patenting firms and by the link between the degree of patent protection and the location of research activity; R&D is traditionally conducted in countries that offer strong patent protection. The number of countries that have introduced patent term restoration measures proves that many governments view patent protection as significant for this sector. Believing that these measures will sustain and improve the climate for R&D in the globally competitive pharmaceutical market, the United States, Japan, Australia and member countries of the European Community have moved to extend the effective patent life of pharmaceutical products to compensate for the erosion of patent terms by the time taken for regulatory approval procedures.

While this country has eliminated its system of compulsory licensing for pharmaceuticals and now ensures that patentees can enjoy market exclusivity until the expiration of their patents, it has not yet considered patent term restoration measures. Canada may, however, be forced to deal with this issue in order to maintain a legislative environment for pharmaceutical patents that is competitive with that of other major industrial nations.

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*BLUE	25072	BLEU*
RL. BLUE	25073	RL. BLEU
*GREY	25074	GRIS*
GREEN	25075	VERT
RUST	25078	ROUILLE
EX RED	25079	ROUGE

ACCO CANADA INC.
WILLOWDALE, ONTARIO

* INDICATES 75% RECYCLED 25% POST-CONSUMER FIBRE

*SIGNIFIE 75 % FIBRES RECYCLÉES, 25 % DÉCHETS DE CONSOMMATION

BALANCE OF PRODUCTS 25% RECYCLED

AUTRES PRODUITS: 25 % FIBRES RECYCLÉES

ACCO® USA
WHEELING, ILLINOIS 60090
ITEM NO. 25072
MADE IN USA
0 50505 25072 1
LT. BLUE/BLEU/AZUL CLARO